

HOUSE BILL 1650
By McMillan

AN ACT to amend Tennessee Code Annotated, Title 4; Title 8; Title 12; Title 41; Title 53; Title 56; Title 63; Title 68 and Title 71, relative to prescription drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 68, Chapter 1, is amended by the following as a new part:

Section 68-1-2101.

(a) There is established in the department of health a state formulary committee.

The committee shall make recommendations regarding a preferred drug list (PDL) to govern all state purchases of prescription drugs.

(b) In making appointments to the committee, the appointing authorities shall strive to ensure the committee's membership is representative of the state's geographic and demographic composition, with appropriate attention to the representation of women and minorities.

(c) The state formulary committee shall be composed of thirteen (13) members. Except for initial appointments, members shall be appointed to three-year terms.

Members shall be appointed as follows:

(1) The governor shall appoint one (1) researcher with expertise in pharmacology from the University of Tennessee Health Science Center, one (1) representative from the Vanderbilt University Medical School, one (1) practicing psychiatrist participating in the TennCare program from a list of three (3) candidates submitted by the Tennessee Psychiatric Association, one (1) practicing nurse practitioner from a list of three (3) candidates submitted by the Tennessee Nurses Association, one (1) pharmacy director from a TennCare managed care organization; one (1) chief medical officer from a TennCare managed care organization, and one (1) practicing physician participating in the TennCare program from a list of three (3) candidates submitted by the Tennessee Chapter of the AARP. For initial appointments the governor shall appoint two (2) members to a one-year term, two (2) members to two-year terms, and three (3) members to three-year terms.

(2) The governor, the speaker of the house of representatives, and the speaker of the senate shall each appoint one (1) physician who participates in the TennCare program from a list of seven (7) candidates submitted by the Tennessee Medical Association. For initial appointments, the governor's appointment shall be to a one-year term, the speaker's of the house of representatives appointment shall be to a two-year term, and the speaker of the senates appointment shall be to a three-year term.

(3) The governor, the speaker of the house of representatives, and the speaker of the senate shall each appoint one (1) practicing pharmacist who participates in the TennCare program from a list of seven (7) candidates submitted by the Tennessee Pharmacists Association. For initial appointments, the governor's appointment shall be to a one-year term, the speaker's of the

senates appointment shall be to a two-year term, and the speaker's of the house of representatives appointment shall be to a three-year term.

(d) The members of the committee shall elect a chair and a vice chair at the first committee meeting. The committee shall hold chair and vice-chair elections at the first meeting of each subsequent fiscal year beginning in fiscal year 2005. The commissioner of health shall call the first meeting of the committee.

(e)

(1) The chair of the committee shall call all meetings of the committee and preside at all regular and special meetings of the committee, appoint members to any subcommittees established by the committee, prepare agendas with the assistance of staff from the University of Tennessee Health Science Center and the state pharmacy benefit manager, and notify members of their removal from the committee.

(2) The vice chair shall exercise all powers of the chair in the event of the absence or inability of the chair to serve and shall perform other duties as the chair may assign to the vice chair.

(f) Committee meetings shall follow Robert's Revised Rules of Order.

(g) Committee meetings shall be subject to the provisions of title 8, chapter 44.

(h) Committee decisions shall be made based on affirmative votes of the majority of members present at official meetings.

(i) The committee shall keep minutes of all meetings including votes on all decisions regarding drugs to be included on the state preferred drug list.

(j) A quorum shall be established by the presence of seven (7) committee members present at an official meeting.

(k) The chair may request that other physicians, pharmacists, or medical experts who participate in various sub-specialties act as consultants to the committee as needed.

(l) Vacancies shall be filled by the appointing authority of the member in the same manner as full terms for the remainder of the unexpired term.

Section 68-1-2102. A state formulary committee member shall be removed by the commissioner of health from the committee for any of the following causes:

(1) Absence from two (2) consecutive meetings without contacting the chair or the vice chair with a satisfactory explanation;

(2) Absence from two (2) meetings in a single year without contacting the chair or the vice chair with a satisfactory explanation;

(3) Receiving unreported compensation from pharmaceutical manufacturers or entertaining individual lobbying or marketing from pharmaceutical manufacturers that would call into question a member's impartiality in determining drugs to include on a state preferred drug list.

Section 68-1-2103.

(a) Members of the state formulary committee shall not enter any financial relationships with pharmaceutical manufacturers or their affiliates during their tenure on the state formulary committee. A member shall not entertain individual lobbying or marketing, or participate in any other activity or discussions with pharmaceutical manufacturers or their representatives that would call into question the member's impartiality in determining drugs to include on a state preferred drug list.

(b) A conflict of interest exists when the member has a personal, professional or monetary interest in a matter under consideration by the state formulary committee. Persons being considered for membership on the state formulary committee shall disclose if they have a real or apparent conflict of interest. Conflicts of interest may

include, but shall not be limited to, being the recipient of a grant, hired as a consultant, being part of a speakers bureau, a major stock holder, or the recipient of other financial support from an organization likely to benefit financially from the outcome of the state formulary committee's work.

(c) Members shall dispose of matters before the committee in an unbiased and professional manner. In the event that a matter being considered by the committee presents a real or apparent conflict of interest, such members shall disclose the same to the chair and recuse themselves from any official action on the matter.

(d) Members shall receive no compensation for their service on the state formulary committee other than an hourly rate and roundtrip mileage from their points of origin to meeting locations as approved by the commissioner of finance and administration.

Section 68-1-2104.

(a) The state formulary committee shall submit recommendations for major drug classes to be included on a state preferred drug list (PDL) to the state executive formulary committee by August 1, 2003. The PDL shall include both specific and general recommendations for drugs to be included on the PDL. The PDL shall also include recommendations regarding computerized, voice, and written prior authorization and step therapy.

(b) The committee shall submit recommendations for all other drug classes to be included on a state PDL to the state executive formulary committee, established by Section 68-1-2106, by January 1, 2004.

(c) Following initial recommendations for the state PDL, the state formulary committee shall meet as needed to review the state PDL and recommend potential changes.

Section 68-1-2105. Until a contract has been established with a state pharmacy benefit manager (PBM), the University of Tennessee College of Pharmacy shall provide clinical research for the state formulary committee on drugs and drug classes discussed at committee meetings. After the state has obtained a PBM contract, the PBM shall provide that information. The PBM shall provide information to be presented at committee meetings to the College of Pharmacy at least one (1) week prior to committee meetings for the College of Pharmacy's review. The College of Pharmacy shall provide additional information as necessary at committee meetings.

Section 68-1-2106.

(a) There is established a state executive formulary committee consisting of five (5) members. The commissioner of finance and administration, the commissioner of health, and the director or deputy commissioner administering the bureau of TennCare shall each appoint one (1) representative to serve on the state executive formulary committee. The chair and vice chair of the state formulary committee shall also serve on the executive formulary committee.

(b) The executive formulary committee shall construct a state preferred drug list (PDL) based on the recommendations of the state formulary committee and drug prices net of rebates obtained through the state pharmacy benefit manager. Due to the confidential nature of pharmaceutical rebates, meetings of the state executive formulary committee are not subject to the provisions of title 8, chapter 44, and the committee shall maintain the confidentiality of all proprietary information it may acquire.

(c) The PDL shall apply to all pharmacy purchases within:

- (1) The TennCare program;
- (2) State group insurance programs;
- (3) The TennCare Rx program; and

(4) Any other pharmacy purchases designated by the department of finance and administration.

SECTION 2. Tennessee Code Annotated, Title 4, Chapter 3, Part 10, is amended by adding the following as new section to be appropriately designated:

Section 4-3-1013.

(a) The department of finance and administration shall contract with a pharmacy benefit manager (PBM) to administer prescription drug programs for the state of Tennessee.

(b) Under the contract, the PBM shall:

(1) Provide information to the state formulary committee to assist in the development of a state preferred drug list (PDL);

(2) Provide claims processing and administrative services for the TennCare program, the state group insurance programs, the TennCare Rx program, and any other pharmacy purchases designated by the department of finance and administration;

(3) Provide data on utilization patterns to the bureau of TennCare, department of finance and administration, TennCare managed care organizations, contract partners for state employee health plans, the University of Tennessee Health Science Center, and other entities determined by the department of finance and administration;

(4) Conduct prospective and retrospective drug utilization review as directed by the department of finance and administration and the bureau of TennCare;

(5) Establish procedures for determining potential liability of third-party payers, including but not limited to Medicare and private insurance

companies, for persons receiving pharmacy services through the state of Tennessee;

(6) Maintain a retail pharmacy network to provide prescription drugs through state programs;

(7) Set pharmacy reimbursement rates and dispensing fee schedules necessary to maintain an adequate retail pharmacy network and increase the cost-effectiveness of state pharmacy purchases;

(8) Negotiate rebates with pharmaceutical manufacturers for prescription drug purchases;

(9) Establish maximum allowable cost (MAC) prices for drugs available in generic form. These prices must be in compliance with federal upper limit (FUL) prices established under 42 U.S.C. Section 1396r-8;

(10) Maintain accounts for local government entities participating in state-sponsored prescription drug programs;

(11) Propose other initiatives to the bureau of TennCare and the department of finance and administration to maintain or improve patient care while reducing prescription drug costs; and

(12) Provide other services as directed by the department of finance and administration.

(c) The PBM contract shall include performance goals and financial incentives for success or failure in attaining those goals.

SECTION 3. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following as a new section:

Section 71-5-194.

(a) The bureau of TennCare shall remove pharmacy services from managed care organization [MCO] contracts and assume direct responsibility for all TennCare pharmacy purchases.

(b) The bureau of TennCare shall implement tiered copayments and prior authorization and step therapy requirements based on the state preferred drug list (PDL).

(c) The bureau of TennCare, through the state pharmacy benefit manager (PBM), shall negotiate manufacturer rebates for TennCare prescription drug purchases. Drug prices may not exceed those guaranteed through 42 U.S.C. Section 1396r-8.

(d) The bureau of TennCare shall implement financial penalties and incentive payments for MCOs that are tied to prescription drug utilization. The bureau may base these penalties and incentives on:

- (1) Prescription drug expenditures per patient;
- (2) Prescriptions per patient;
- (3) Formulary compliance;
- (4) Generic utilization rate; and
- (5) Other measures determined by the bureau.

SECTION 4. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following as a new section:

Section 71-5-195.

(a) If necessary, the bureau of TennCare shall seek a research and demonstration waiver under section 1115 of the federal Social Security Act from the U.S. department of health and human services to create a TennCare Rx program, subject to funding by the general assembly and the terms and conditions imposed by the waiver.

(b) To the extent permitted by federal law or the terms of the waiver, the TennCare Rx program shall provide a prescription benefit to individuals lacking

prescription drug insurance coverage who meet criteria established by the bureau of TennCare and the general assembly in its annual appropriation bill.

(c) To the extent permitted by federal law or the terms of the waiver, the bureau of TennCare shall implement tiered copayments and prior authorization and step therapy requirements for the TennCare Rx program based on the state preferred drug list (PDL).

(d) To the extent permitted by federal law or the terms of the waiver, the bureau of TennCare, through the state pharmacy benefit manager (PBM), shall negotiate manufacturer rebates for TennCare Rx prescription drug purchases. Drug prices may not exceed those guaranteed through 42 U.S.C. 1396r-8.

(e) To the extent permitted by federal law or the terms of the waiver, the bureau of TennCare shall establish an open enrollment period based on appropriations from the general assembly.

(f) To the extent permitted by federal law or the terms of the waiver, the bureau of TennCare may contract with another department or a private entity to conduct eligibility determination. The bureau or a contracted entity shall implement an eligibility determination process to ensure participants comply with eligibility standards set by the bureau and the general assembly.

(g) As permitted by the waiver or federal law, program participants may purchase prescription drugs through pharmacies participating in the state network.

(h) To the extent permitted by federal law or the terms of the waiver, the bureau of TennCare may establish an enrollment fee to defray administrative expenses associated with the program.

SECTION 5. Tennessee Code Annotated, Title 8, Chapter 27, Part 1, is amended by adding the following as a new section:

Section 8-27-104.

(a) The department of finance and administration is authorized to remove pharmacy services from appropriate state contracts and assume direct responsibility for all pharmacy purchases within the state employee health plans.

(b) The department of finance and administration shall hire a pharmacy director to administer the pharmacy benefit for state group insurance programs in association with the state pharmacy benefit manager.

(c) The state insurance committee shall implement tiered copayments and prior authorization and step therapy requirements based on the state preferred drug list (PDL).

(d) The department of finance and administration, through the state pharmacy benefit manager (PBM), shall negotiate manufacturer rebates for state employee health plans prescription drug purchases.

SECTION 6. Tennessee Code Annotated, Title 4, Chapter 3, Part 11, is amended by adding the following as a new section:

Section 4-3-1114.

(a) The department of general services, through the state pharmacy benefit manager (PBM), shall negotiate manufacturer rebates for state wholesale prescription drug purchases.

(b) The department shall implement prior authorization and step therapy requirements based on the state preferred drug list (PDL).

(c) The department of correction shall study the potential cost savings from carving out prescription drug purchases from existing contracts and obtaining prescription drugs through the department of general services.

SECTION 7. Tennessee Code Annotated, Title 4, Chapter 3, Part 10, is amended by adding the following as a new section:

Section 4-3-1013.

(a) The department of finance and administration shall create a program whereby local government entities, including but not limited to county jails, can purchase prescription drugs through state methods at reduced prices.

(b) The department of general services shall sell drugs to participating local entities that have certified pharmacists on staff or require wholesalers contracting with the department of general services to sell prescription drugs to participating local entities at discounted rates.

(c) The state pharmacy benefit manager (PBM) shall establish accounts for participating local government entities that lack certified pharmacists. Participating entities may purchase prescription drugs through pharmacies participating in the state network.

(d) The department of finance and administration shall implement tiered payments and prior authorization and step therapy requirements for participating local entities based on the state preferred drug list (PDL).

(e) All account transactions with cost information on individual drugs shall be confidential and shall not be public records for the purposes of title 10, chapter 7, part 5.

SECTION 8. If a court of competent jurisdiction enjoins, restrains or stays programs authorized by this act, then the department of finance and administration or the bureau of TennCare as appropriate is authorized to proceed to implement as appropriate those portions of this act that have not been lawfully enjoined, restrained or stayed.

SECTION 9. Tennessee Code Annotated, Section 4-29-226(a), is amended by adding the following new items to be appropriately designated:

() State formulary committee;

() State executive formulary committee;

SECTION 10. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the

act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 11. This act shall take effect on becoming a law, the public welfare requiring it.